

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION

PAMELA BUTLER,

Plaintiffs,

VS.

MALLINCKRODT LLC, et al.,

Defendants.

$$\begin{array}{c} ) \\ ) \\ ) \\ ) \\ ) \\ ) \\ ) \end{array}$$

Case No. 4:18-cv-01701-AGF

## Lead Case

**PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR OPPOSITION TO**  
**DEFENDANTS' MOTION TO EXCLUDE THE TESTIMONY OF PLAINTIFFS'**  
**EXPERT JAMES CLARK, PH.D.**

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## **INTRODUCTION**

Dr. Clark should be allowed to offer his opinions because he is qualified to do so and he bases his opinions on reliable scientific methodology. He is an expert toxicologist, exposure analyst, and air modeler. He has studied the issues presented in this case, including the fundamentals of radiation exposure which he first learned in coursework while obtaining his Ph.D., and recently studied once again as he served as an expert in hundreds of cases involving radiation exposure throughout the St. Louis area, both in federal and state court. No court has struck or limited his opinions in any of these cases. He has the requisite knowledge, skill, experience, training, and education to offer his opinions on the levels of radiation Plaintiffs were exposed to throughout the St. Louis area.

Dr. Clark uses reliable methods to support his opinion that Plaintiffs were exposed to considerable amounts of radiation from radioactive waste throughout the St. Louis area via three primary pathways: ingestion, inhalation, and direct exposure to ionizing radiation. Dr. Clark relies on data and methodologies from the published scientific studies, including government reports, to analyze these pathways. He uses the same exposure assessment formulas developed and used by the Agency for Toxic Substances and Disease Registry (ATSDR). The ATSDR validated these formulas using complicated computer software to confirm they are accurate for assessing internal exposure levels caused by coming in contact with the radioactive material. He applies these formulas to the facts and data from this case, including the amount of time these Plaintiffs spent at areas where known radiological contamination was present.

Based on these methodologies, Dr. Clark (and Dr. Hu) are able to determine Plaintiffs were exposed to levels of radiation substantial enough to activate their disease process. This is all Missouri and the Eighth Circuit require to prove causation in a toxic tort case. Plaintiffs are not,

as Defendants demand, required to present a precise exposure level to satisfy their burden of proof, or to calculate exposure above natural background. Because Dr. Clark is qualified and his opinions are based on reliable methodologies and will be helpful to the jury, his testimony is admissible.

### **LEGAL AUTHORITY**

#### **I. Expert testimony is to be liberally admitted and only opinions that are fundamentally unsupported by scientific methodology should be excluded.**

The Eight Circuit repeatedly emphasizes courts must exercise their gate-keeping function pursuant to Rule 702 and *Daubert* to exclude only evidence that is fundamentally unsupported by any scientific methodology. Absent this high threshold, courts must liberally admit expert opinion and permit any flaws to be addressed via cross examination:

While we adhere to this discretionary standard for review of the district court's Rule 702 gatekeeping decision, cases are legion that, correctly under *Daubert*, call for the liberal admission of expert testimony. *See, e.g., United States v. Finch*, 630 F.3d 1057, 1062 (8th Cir.2011) (holding that we resolve doubts about the usefulness of expert testimony in favor of admissibility); *Robinson v. GEICO Gen. Ins. Co.*, 447 F.3d 1096, 1100 (8th Cir.2006) (holding that expert testimony should be admitted if it “advances the trier of fact's understanding to any degree” (quotation omitted)); *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir.2001) (Rule 702 “clearly is one of admissibility rather than exclusion” (internal quotation omitted)); *Wood v. Minn. Mining & Mfg. Co.*, 112 F.3d 306, 309 (8th Cir.1997) (holding that exclusion of expert's opinion is proper “only if it is so fundamentally unsupported that it can offer no assistance to the jury” (internal quotation omitted)). Further, district courts are admonished not to weigh or assess the correctness of competing expert opinions. *Wyeth*, 686 F.3d at 625. As long as the expert's scientific testimony rests upon “good grounds, based on what is known” it should be tested by the adversary process with competing expert testimony and cross-examination, rather than excluded by the court at the outset. *Daubert*, 509 U.S. at 590, 596, 113 S.Ct. 2786.

*Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 562 (8th Cir. 2014).

Attacks directed at the factual basis for expert opinion generally give rise to issues of credibility, not admissibility. *Tussey v. ABB, Inc.*, 746 F.3d 327, 337 (8th Cir. 2014) (additional citations omitted). “Only if the expert’s opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded.” *Osment Models, Inc. v. Mike’s Train*

*House, Inc.*, 2010 WL 4721223, at \*2 quoting *Wash Solutions, Inc. v. PDQ Mfg., Inc.*, 395 F.3d 888, 895 (8th Cir. 2005) (additional citations omitted). Credibility issues are properly addressed through cross-examination by the opposing party. *Id.*

The Eighth Circuit’s requirement that expert testimony be liberally admitted also extends to questions regarding a witness’ qualification. “[T]he relative skill or knowledge of an expert goes to the weight of that witness's testimony, not its admissibility.” *Fed. Crop Ins. Corp. v. Hester*, 765 F.2d 723, 728 (8th Cir. 1985). As long as a witness has the qualifications to advance the jury’s understanding of an issue *to any degree*, the Eighth Circuit holds the witnesses must be allowed to testify. “Rule 702 only requires that an expert possess ‘knowledge, skill, experience, training, or education’ sufficient to ‘assist’ the trier of fact, which is ‘satisfied where expert testimony advances the trier of fact's understanding to any degree.’” *Robinson v. GEICO Gen. Ins. Co.*, 447 F.3d 1096, 1100 (8th Cir. 2006) (quoting 29 CHARLES ALAN WRIGHT & VICTOR JAMES GOLD, *FEDERAL PRACTICE AND PROCEDURE: EVIDENCE* § 6265 (1997)). “Gaps in an expert witness's qualifications or knowledge generally go to the weight of the witness's testimony, not its admissibility.” *Id.*

### **QUALIFICATIONS**

Defendants’ Brief ends where the Court’s analysis should start—with Dr. Clark’s qualifications. James Clark, Ph.D. is an expert in toxicology, exposure analysis, and air modeling. He has multiple graduate degrees and decades of experience in his field. He earned his Bachelor’s Degree in Biochemical and Biophysical Sciences from the University of Houston in 1987; his Master's Degree in Environmental Health Sciences from the University of California at Los Angeles, School of Public Health in 1993; and his Ph.D. in Environmental Health Sciences from the University of California at Los Angeles, School of Public Health in 1995. (Exhibit A, Dr.

Clark's C.V.) He has trained and is certified under OSHA 29 CFR 1910.120 for Hazardous Waste Operations 81 Emergency Response. He has been an active member of various professional societies, including the American Public Health Association (APHA), the International Society of Environmental Forensics (ISEF), and the Association for Environmental Health and Sciences (AEHS).

From 1987 through 1992, Dr. Clark worked as a toxicological researcher at the University of California at Los Angeles, Department of Medicine, Pulmonary Division, under the supervision of physicians who were investigating the pulmonary toxicity of air pollutants. His research included epidemiological evaluations of populations exposed to criteria pollutants, the potentiating effects of inhaled beta-agonists on the hyper-reactive responses of asthmatic patients, patients with chronic—obstructive pulmonary disease (COPD), and patients with interstitial lung disease to criteria pollutants including ozone and oxides of sulfur.

While a graduate student at UCLA, he worked for environmental consulting companies involved in human health risk assessments and toxicological evaluations of evaluation contaminants. Since 1996, after completing his doctoral thesis on a novel multi-pathway risk model, he has worked at several environmental consulting firms, evaluating the toxicological impacts of contaminants in selected populations, coordinating regional air pollution studies, performing exposure assessments and numeric risk assessments, supervising remedial investigations and removal actions, and acting as the Corporate Health and Safety Officer.

Dr. Clark has spent over 25 years studying the toxicological effects of many chemicals as part of his training in toxicology and daily work experience as a Toxicologist. His work experience includes considerable risk assessment, evaluation of environmental toxic exposures, design and execution of environmental monitoring and health assessment studies, and modeling of exposure

to toxic compounds. He has also participated in and/or directed numerous air/emission—related risk assessments, including toxicological assessment of benzene and other volatile substances from mobile and stationary sources and gasoline-related sources. He continues to research the effects of contaminants in the environment and has presented those results at numerous professional assemblies and in a recently published college textbook.

Dr. Clark has served as an expert radiation dose and exposure witness, including authoring reports and giving deposition testimony on behalf of plaintiffs in hundreds of cases. No court has ever struck or limited his opinions in a radiation case. His extensive knowledge, skill, experience, training, and education in toxicology, exposure analysis, and air modeling gives him the expertise to offer his opinions in those cases, just as they do in cases involving exposure to other toxins and just as they do in this case. Dr. Clark is qualified to offer his opinions.

### **ARGUMENT**

Despite his qualifications and reliable methodology, Defendants insist the Court must exclude Dr. Clark from testifying. Defendants argue Dr. Clark must have degrees specific to radiation to qualify as an expert witness, even while admitting he studied the concepts relevant to this case. Defendants also insist that because the ATSDR study's results apply to the community as a whole, this somehow nullifies the steps the ATSDR took to confirm the reliability of their formulas to estimate individual dose and risk by comparing them against complex computer models. Finally, Defendants ignore the jury's role in this case and ask the Court to exclude Dr. Clark's testimony because it is based on certain factual assumptions the Defendants disagree with. All of this is, at the most, fodder for cross examination. None of it touches on admissibility.

#### **I. The Basis For Dr. Clark's Opinions Are Consistent With The ATSDR.**

Dr. Clark bases his opinions on the wealth of published data and studies concerning the radioactive material at issue in this case. This includes the ATSDR's Public Health Assessment of the community exposure related to Cold Water Creek. (**Def. Exh. C**). In 2019, the ATSDR published its final report evaluating "whether people playing or living near Coldwater Creek have or had harmful exposures to radiological or chemical contaminants from the creek." (**Def. Exh. C**, p. ii) Dr. Clark relies on the same methodologies the ATSDR uses in this report. Specifically, he uses the same formulas for calculating dose that the ATSDR uses.

The ATSDR ensured these formulas were accurate by validating them against complex computer models. Based on this, the scientists at the ATSDR are confident their formulas provide a reasonable estimate of both dose and risk:

The process used by ATSDR is reasonable for the purposes of our public health assessment. ATSDR recognizes that EPA's 2011 lifetime attributable risk coefficients were designed to be used with absorbed dose in a given year and then integrated over the years of exposure and dose. For multiple years of intake this becomes very complicated, typically requiring specialized computer programs that cannot be easily explained to or replicated by members of the public. In contrast, ATSDR estimated the committed dose to age 70 for every year of intake separately, and applied that committed dose in the year the intake occurred. **This simplifies the calculations and allows clear presentation of the estimated dose and risk for each year an intake occurred.**

To test how ATSDR's method compared with integrative methods, we used the AcuteDose code to estimate absorbed organ-specific doses for each year to age 70 and applied the 2011 lifetime attributable risks to determine lifetime cancer risks resulting from 33 years of intake, using the assumptions developed for the Coldwater Creek evaluation [136]. **ATSDR's simplified method gives cumulative dose estimates and lifetime cancer risks generally comparable with the more complicated approach. We concluded that our methodology would be a reasonable approximation for estimating lifetime risks.** We recognize that this approach would not be used in a detailed dose reconstruction. We believe the improved accessibility of the calculations for the general public outweighs any inaccuracies introduced by our method.

(**Def. Exh. C**, F-11 (emphasis added)).

Defendants cite certain excerpts from Dr. Clark's depositions in related cases, but they fail to include the portions of these depositions where Dr. Clark confirmed the methodology employed by the ATSDR is a reliable alternative to the more complicated reconstruction models that require specialized computer software:

**Q:** All right. Dr. Clark, before the break, we were talking about the ATSDR method from Coldwater Creek that you used in this case. That's the method you used to calculate Mr. Czapl's dose and risk is that fair?

**A: Correct.**

**Q:** Okay. That method is actually a simplified method for calculation, that's what the ATSDR said, correct?

**A: Correct.**

**Q:** And, in fact, didn't the ATSDR say that that method was inappropriate for calculating doses to individuals?

**A:** That method was inappropriate if somebody was assuming -- did not put in cite specific information. **So the method is appropriate and they went through and validated the dose and the calculated risk and found that it was within 10 percent of the acute model that others have used,** acute exposure model that they have used. So they had high confidence that the doses and the risk that they were - - had presented in that community exposure was appropriate, so the -- **just taking the results of the report and applying it to a particular individual wouldn't be appropriate but taking the method and putting in specific information would be appropriate.**

(Def. Exh D, Deposition of Dr. Clark, *Czapla et al., v. Republic Services Inc., et al.*, pp. 33:5-34:5 (emphasis added)).

Dr. Clark applies the methodology in the ATSDR report to the facts and data specific to the Plaintiffs' exposures. Likewise, instead of estimating the ages of a typical resident of the community or how much time one of these typical residents spent in and around Cold Water Creek, Dr. Clark uses the information specific to each Plaintiff. Based on all of this, he is able to apply the reliable methodology used by the ATSDR to the facts of this case.

### A. Dr. Clark's Use of the ATSDR's Methodology is Consistent With Its Intended Purpose

Defendants argument that Dr. Clark's methodology contradicts the ATSDR's report is also demonstrably false. When Dr. Clark utilized the data from the ATSDR's draft community screening report it did contain the language "not to be used for a detailed dose reconstruction." (See **Def. Exhibit B**, P.138:12-22). However, the ATSDR's final report did not include that strict prohibition. (See **Def. Exhibit C**). While Defendants selectively quote from ATSDR's draft report to imply ATSDR conceded its method is not accurate, the opposite is true. A full reading of the ATSDR's defense of the method it uses reveals the ATSDR confirmed that its method "simplifies the calculations and allows clear presentation of the estimated dose and risk for each year an intake occurred." (**Def. Exhibit C**, F-11 (emphasis added)). The ATSDR is unequivocal in this respect: "ATSDR's simplified method gives cumulative dose estimates and lifetime cancer risks generally comparable with the more complicated approach. We concluded that our methodology would be a reasonable approximation for estimating lifetime risks." *Id.*

Moreover, in its final report, the ATSDR specifically rejected the same criticism—from the same hired experts<sup>1</sup>—Defendants make here. "ATSDR disagrees with the assertion that our use of the committed dose to age 70 resulted in gross overestimates of risk." *Id.*, at F-58. The ATSDR compared its formulas to other accepted exposure methods and found them to be accurate. "To test how ATSDR's method compared with the method suggested by the commenter, we used the AcuteDose code to estimate absorbed organ-specific doses . . . [w]e found that the doses to age 70

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<sup>1</sup>The irony of Defendants' reliance on these public comments cannot be understated. These comments were submitted by *Defendants' retained expert witnesses* in this case. (As disclosed in their comment, "These comments have been prepared by Risk Assessment Corporation, its team members, and additional scientists and medical physicians. With the exception of Dr. Keith F. Eckerman, an expert in radiation dosimetry and radiation risk calculations, the authors of this review were part of an investigation of these sites that was funded by Mallinckrodt Pharmaceuticals." (Def. Exh. C., Pg. F-36 (emphasis added)). Whatever controversy surrounding the ATSDR's methodology is manufactured by the Defendants solely for the purpose of litigation.

from the cumulative exposure were very close (within 10%) to our method.” *Id.*, at F-59, *see also* f-11 (“ATSDR’s simplified method gives cumulative dose estimates and lifetime cancer risks generally comparable with the more complicated approach. We concluded that our methodology would be a reasonable approximation for estimating lifetime risks.”).

This is in stark contrast to the facts of *Good v. Flour Daniel Corp.*, 222 F. Supp. 2d 1236, 1245 (E.D. Wash. 2002) which Defendants rely on here. In *Good*, the article plaintiff’s expert relied on explained that it was scientifically impossible to perform cytogenetic analysis to estimate exposure to penetrating forms of radiation for the non-penetrating alpha radiation. *Id.* at 1244. The Eastern District of Washington’s decision is correct, an expert’s opinions cannot contradict basic principles of science. Here, the ATSDR defended the scientific principles behind its methodology and Dr. Clark’s opinions are consistent with the ATSDR’s approach.

#### **B. Dr. Clark Did Not Create the ATSDR’s Methodology For Litigation**

Despite hiring experts to attack the ATSDR’s methodology for the purpose of litigation, Defendants claim Dr. Clark is the one creating methodology for the purpose of litigation by relying on the ATSDR’s methods. Defendants take umbrage at Dr. Clark’s use of different methodologies he used in past related litigation for dose reconstruction. His past use of other methodologies does not render his reliance on the ATSDR’s methodology unsound, but merely demonstrates Defendants’ readiness to attack whatever methodology Dr. Clark relies on, even as he looks to more recent and detailed studies of Coldwater Creek contamination. In previous litigation, Defendants’ criticized his initial use of RERAD model for dose reconstruction. When he utilized another model, GENII, Defendants paid its creator to criticize him for that.<sup>2</sup> As Dr. Clark continued to utilize stronger and more reliable methodologies, Defendants continue to move the

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<sup>2</sup> Defendants retained Dr. Nappier for the simple purpose of condemning Dr. Clark’s use of the GENII model.

goalposts back further and further. Again, the ATSDR verified that its methodology is a reliable way to determine dose and risk<sup>3</sup>. (**Def. Exh. C**, F-59, *see also* F-11).

Defendants also argue that the difference in the bone coefficient between the ATSDR's draft and final report render his opinions so incorrect as to be "fundamentally unsound." None of these Plaintiffs are claiming any type of bone cancer. At his deposition, Dr. Clark confirmed this change does not significantly bear on the Plaintiffs' ultimate effective doses:

Q. So then all of the bone factor doses that you have in your reports are all overestimated; correct?

**A. Yes.**

Q. And that would also overestimate all of the effective doses; correct?

**A. No, because the effective -- it's only attributable to the bone dose, not to all the effective doses.**

Q. How do you --

**A. The effective dose is specific to each organ. So it's only for the bone, not for the breasts, not for the brain, not for anything else.**

Q. The effective dose sums up all the organ doses; correct?

**A. There were 12 organ doses that were evaluated in that, yes.**

Q. And one of those was bone; correct?

**A. Let me look. Yes. The bone surfaces, which account for 3 percent.**

Q. That wasn't my question. My question was: Because the bone -- the dose to the bone was overestimated, the effective dose would also be overestimated; correct?

**A. And my answer is the same, that, yes, it would be affected and the bone dose only accounts for 3 percent of the impact on the whole body dose.**

(**Def. Exh. B**, Pg. 268:1-269:4). The ATSDR agrees with Dr. Clark that this change is not significant:

Q. It says, "The correction factor for high LET radiation applicable to the Lifetime Attributable Risk (LAR) coefficient for bone cancer is incorrect, resulting in all bone cancer risks being a factor of 10 too high." Do you see that?

**A. I do.**

Q. And then ATSDR's response is, "ATSDR agreed that the Lifetime Attributable Risk coefficient for bone surface should not have been multiplied by 10. The results mentioned

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<sup>3</sup> As Dr. Clark explained in his deposition, while the ATSDR methodology is reliable, it's also true that using other models was simply not an option, given the time constraints imposed by the Court and the fact that the *McClurg* settlement prohibited the use of, or even access to, the analysis of other plaintiff experts. Def. Exh. B, 46:14-48:22. Case Management Order No. 14 was entered days after Plaintiffs filed suit. Plaintiffs' objections to it were overruled. Plaintiffs and their experts complied with the order. If Defendants believed the reports were deficient, the order provided the procedure was to alert Plaintiffs and give them an opportunity to fix it. Because Defendants never did so, they should not be allowed to now seek exclusion based on the use of the ATSDR's methodology.

in the previous response to PCRAC 1030 is incorporated in this correction. We have updated the risk table in discussion in the report to reflect updated risk."

**A. "This change does not affect our overall conclusions," yes.**

(Def. Exh. B, Pg. 266:15-267:6). None of these Plaintiffs are claiming any type of bone cancer. The difference in cancer coefficients is insignificant as to Dr. Clark's effective dose calculations. Moreover, both are within the range of doses produced in both the ATSDR's Health Assessment for Cold Water Creek contamination and the USEPA Baseline risk Assessment (*See Def. Exh. C*, Pg.22, Table 2, and Pg. F-10; *See Exhibit B*, Pg. 10-11, Q24). Under the methodologies utilized by both the EPA and ATSDR, it is reasonable to use differing cancer coefficients to present a range of possible doses an individual could expect from a radionuclide exposure. Perhaps this is a point for cross examination, but it does not warrant exclusion.

**II. Defendants' Disagreements with the Factual Assumptions Supporting Dr. Clark's Opinions are, at Best, Matters for Cross Examination.**

Dr. Clark's estimates of each Plaintiff's exposures and other factual assumptions he makes are matters for cross examination, not exclusion. "As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination. Only if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded." *Hartley v. Dillard's, Inc.*, 310 F.3d 1054, 1061 (8th Cir. 2002) (quoting *Bonner v. ISP Technologies, Inc.*, 259 F.3d 924, 929 (8th Cir. 2001)—30 (8th Cir.2001) (in turn quoting *Hose v. Chicago Nw. Transp. Co.*, 70 F.3d 968, 974 (8th Cir. 1995) (internal citations and quotations omitted)).

As long as an expert uses a reliable methodology, the veracity of the assumptions she makes in employing that methodology are to be addressed in cross examination. For instance, in 2007 the Eighth Circuit held plaintiff's economist was permitted to testify despite defendant's objection that

“the key assumption upon which his opinion is based, essentially that the relevant market is a two supplier market, is false and ignores the existence of significant competition in the market.” *Synergetics, Inc. v. Hurst*, 477 F.3d 949, 955 (8th Cir. 2007). The court held defendant’s issue with this faulty assumption did not disqualify the opinion, rather defendant could be permitted to cross examine the expert and present its own expert testimony:

Vollmar's testimony was not so fundamentally unsupported that it could offer no assistance to the jury. He explained his methodology in calculating the damages, and the Appellants had the opportunity to challenge Vollmar's assumptions and methodology, both through cross-examination and by presenting their own expert witness on damages. While other methods for calculating damages may be available, so long as the methods employed are scientifically valid, *Appellants' mere disagreement with the assumptions and methodology used does not warrant exclusion of expert testimony.*

*Id.* (emphasis added) (citing *Daubert*, 509 U.S. at 596, 113 S.Ct. 2786 (“Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.”); and *EFCO Corp. v. Symons Corp.*, 219 F.3d 734, 739 (8th Cir.2000) (no abuse of discretion in allowing plaintiff's expert witness to testify as to damages where defendant's expert, who disputed plaintiff's expert's methodology, also testified; jury left with ultimate decision as to which damages theory was more sound)).

Here, Defendants argue Dr. Clark’s opinions ignore the information contained in Plaintiffs’ court-ordered questionnaires and depositions. Dr. Clark’s reports were due before Plaintiffs’ deposition could be taken. He reviewed them afterwards, and chose not to amend his reports. But his reports do consider the information in the questionnaires. Before authoring his reports, he reviewed them “multiple times ... reread them several times.” (**Def. Exh. B**, 51:18-19). As is his custom, he also personally interviewed each Plaintiff to determine their exposures to radionuclides.

(*Id.*, B, Pg. 9:5-13; 51:10-53:8). He explains why he finds this method more reliable than the adversarial deposition setting:

[D]epositions are scary things. So their recall of the events during a deposition, I found over the years that particularly people who have never had their deposition before can be a little stilted. And that when folks are able to sit and kind of think about it and write things down, then that story becomes very clear of what's going on. They're answering questions specific to what you guys are asking, and I think the approach of interviewing through the paper and then kind of following back up with those has been the most helpful to me.

(*Id.* at Pg. 54:6-17). Ultimately, the total time each Plaintiff spent at contaminated areas and activities they engaged in there are questions of fact for the jury. Dr. Clark's assumptions on these issues are not without foundation—they are supported by the Plaintiff questionnaires, his personal interviews with the Plaintiffs, the ATSDR's report and assumptions made in therein, and his reading of the depositions to understand if he needed to reassess his own assumptions. He fully explains this method, including how he addresses any discrepancies. Hence, the accuracy of these factual assumptions, used while employing reliable methodologies, are matters for the jury.

Next, Defendants argue Dr. Clark's reliance on the ATSDR's particulate emission factor (PEF) overstated the Plaintiffs' doses. This is again another argument conjured up by Defendants' retained experts that the ATSDR rejected. Defendants' experts disputed the ATSDR's use of a PEF for the Coldwater Creek area that was developed for Colorado ATV trails as completely unrealistic and misleading for activities such as riding bikes and gardening. (**Def. Exhibit C**, Pg. F-49 – F-50). Highlights from the ATSDR's response in defense illustrates the appropriateness of Dr. Clark's reliance on its PEFs:

ATSDR response: **ATSDR disagrees that the PEF used to estimate inhalation during activities is unrealistic.** Activities on soil are known to result in suspension of soil or dust particles directly into the breathing zone of the person doing the activity. The concentration of contaminants in the activity-generated "personal dust cloud" can be orders of magnitude greater than that predicted by models of wind-

blown dust, such as EPA's standard soil suspension value. **Higher soil suspension factors are appropriate for estimating inhalation exposures from activities.**

....

Although the selected PEF was derived for ATV riding, **it is consistent with the studies described above for activities including child play and yard work.** We applied the PEF to all relevant soil contact activities at Coldwater Creek during the time the activity was occurring, as described in the report.

....

**The selected PEF is not inconsistent with standard assumptions used by radiological professionals and experimental data on resuspension of radionuclide particles.**

*Id.* at F-50 – F-51 (emphasis added). The ASTDR stated that the use of PEFs derived for ATV riding is consistent with activities including child play and yard work and does not result in an unrealistic inhalation estimate. Therefore Dr. Clark's opinions relying on those same PEFs to estimate Plaintiffs' exposures for child play and yard work is consistent with the ATSDR's approach and is not grounds for exclusion.

Because evidence exists to support each assumption Dr. Clark makes in forming his opinions, Plaintiffs have the right to present these opinions to the jury. Dr. Clark's testimony should not be excluded.

### **III. Defendants' "Error Rate" of 83% is a Meaningless Number Created by Defendants' Experts for the Purpose of Intentional Confusion.**

Neither the ATSDR's methodology or Dr. Clark's calculations have an 83% error rate. This is an intentionally misleading and ultimately meaningless number created by Defendants' experts. Defendants' experts arrive at this number by categorizing each tab from every spreadsheet Dr. Clark produced to support his calculations as either containing an error, or not. These "errors" are often subjective and meaningless, having no bearing on his calculations. As just one example, Defendants count the two tabs for Pamela Butler—Recreational Present and Residential Present—

as containing errors because she has no present exposure. But this is not an error—the tabs confirm that she has no present exposure. Exhibit C.

The rest of the errors Defendants’ experts complain about include their disagreements with such things as the assumptions underlying the ATSDR report (e.g., the particulate emission factor (PEF) for ATV riding), the assumptions Dr. Clark makes (e.g., the amount of time Anthony Hines spent in the creek), and the inclusion of calculations that have no bearing on the organ at issue or overall opinions (e.g., calculating the amount of exposure to Ms. Butler’s testes). If Defendants’ experts have even the slightest disagreement with any part of a tab—as they claim they do for 64 out of 76 of them (83%)—it counts as an “error.” This process tells one nothing about the reliability of Dr. Clark’s opinions.

#### **IV. *Daubert* Specifically Approved of Admitting Expert Opinions in the Face of an 83.33% Error Rate.**

Defendants’ made-up error rate is certainly not something “*Daubert* requires this Court to consider,” as Defendants claim. But even if it did, *Daubert* specifically held this exact error rate does not warrant exclusion. In *Daubert*, the court addresses error rate as a factor that may be considered by citing with approval to a case involving “the error rate of spectrographic voice identification technique.” *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 594 (1993) (citing *United States v. Smith*, 869 F.2d 348, 353–354 (7<sup>th</sup> Cir. 1989)). In *Smith*, the Seventh Circuit upheld the trial court’s decision to admit expert opinion based on this voice identification technique even in the face of two studies claiming this technique suffered from error rates “of 62.7 percent and 83.33 percent respectively.” *Smith*, 869 F.2d 348, 354 (7<sup>th</sup> Cir. 1989).

And, as *Smith* and *Daubert* make clear, the relevant error rate is of the underlying methodology the expert opinion at issue is based on, not what one hired expert computes regarding another hired expert’s opinions. And the ATSDR’s methodology has withstood the test of peer-

review. After it published its draft report, the ATSDR accepted public comments and criticisms to consider before issuing its final form. Knowing Dr. Clark relied on the ATSDR's methodology for his opinions in this case, Defendants' own experts submitted detailed criticisms of the ATSDR's approach and conclusions regarding exposures estimates for the community. The ATSDR responded fully to each criticism Defendants' experts levied. And after this litigation inspired peer-reviewed process conducted Defendants' own experts, the ATSDR stated, "[w]e concluded that our methodology would be a reasonable approximation for estimating lifetime risks." *Id.* (**Def. Exhibit C**, f-11 (emphasis added)). Thus, the ATSDR's methodology Dr. Clark relies on here has been challenged in an objective sense, it has been subject to peer review, and considering Defendants' experts were the rare dissenters in those comments, been generally accepted in the scientific community.

Again, Defendants' disagreement with Dr. Clark's calculations is not the focus of the Court's inquiry here. The focus should be whether or not the ATSDR's methodology he used is reliable. The ATSDR defended its methodology and concluded it is a reliable method to approximate risks of developing cancer based on exposures to radionuclides from Cold Water Creek. Therefore Dr. Clark's opinions based on that methodology should not be excluded.

#### **V. Dr. Clark's Calculations Can Be Reproduced**

Dr. Clark produced the information Defendants now complain about shortly after his deposition, and Defendants never complained this production was inaccurate, incomplete, or sought to depose Dr. Clark a second time. And, to be clear, his calculations can be reproduced. In fact, by suggesting that they cannot be, while at the same time claiming to have calculated an error rate, Defendants are taking two positions inherently at odds with each other. Either their experts

were able to reproduce his calculations with an error rate, or they are unable to be reproduced. Defendants' attempt to have it both ways is untenable.

Dr. Clark explained his calculations, including how they can be reproduced. He used ProUCL, a software "developed by Northrop and approved by the USEPA." Def. Exh. B, 78:2. He used only the publicly available soil and sediment sampling data:

Q. So when you put in to ProUCL the sample with the value, how many samples did you use?

**A. All of the samples that would have been available for the soils or the sediment listed by U.S. Army Corps.**

(Def. Exh. B, Pg. 79: 1-6). Anyone with ProUCL can use the publicly available data to reproduce Dr. Clark's calculations.

Defendants do not dispute this, but instead complain that Dr. Clark did not produce his ProUCL inputs until after his deposition. First, this is a distraction. The only ProUCL input values Defendants complain about are the input values for the 95% UCL for Thorium-230. Dr. Clark calculates this number to be 62.9 pCi/g, whereas Cotter's expert, Jason B. Miller, puts it at 61 pCi/g. Exhibit D, Expert Report of Jason B. Miller, p. 24, n.10. This is not a significant enough difference to warrant exclusion, even if Dr. Clark withheld his inputs.

But of course Dr. Clark did not withhold his inputs. Plaintiffs produced Dr. Clark's report in April of 2019, six months before Dr. Clark's deposition. Plaintiffs produced these reports pursuant to the Case Management Order No. 14 which, among other things, requires all Plaintiffs to serve case-specific expert reports within 60 days of filing. Doc. 741, p. 9. In this order, the Court gave Defendants a procedure to address any deficiencies in these reports should they find them inadequate, including giving notice of the deficiency via email or fax and a requirement to meet and confer following Plaintiffs' failure to cure the deficiency. *Id.*, at 11.

Defendants never complained that the failure to produce the ProUCL input data did not comply with the Court's requirements. Even after Dr. Clark's deposition, when Plaintiffs quickly provided the requested information, Defendants never gave "notice of such failure by email or fax," never "provided thirty (30) additional days to cure such deficiency," and never attempted to "meet and confer with Plaintiff." *Id.* Instead, Defendants waited two years to lob over-generalized complaints, without any specifics, for the first time in a *Daubert* motion. This litigation tactic violates the Court's October 2018 order, and does not change the reality that Dr. Clark's calculations are reproducible and, for the one value Defendants complain about, near identical to Cotter's own expert's value. Exclusion of Dr. Clark's testimony is not warranted.

## **VI. Dr. Clark's Opinions Are Consistent with Missouri and Eighth Circuit Law Regarding Causation**

### **A. Missouri and Eighth Circuit Law Do Not Require Plaintiffs to Prove Exposures Beyond a Specific Threshold Level**

Defendants erroneously argue that Plaintiffs must show they were exposed to radiation in an amount above "natural background" radiation to satisfy their burden of proof. (Def. Motion Pg. 18). However, neither the Eighth Circuit nor Missouri limits the exposure evidence an expert can consider to only what can be mathematically computed. To the contrary, a plaintiff does "not need to produce a mathematically precise table equating levels of exposure with levels of harm in order to show that she was exposed to a toxic level of [the chemical at issue]." *Bonner v. ISP Technologies, Inc.*, 259 F.3d 924, 928 (8th Cir. 2001).

In *Bonner*, the expert "was unable to offer a threshold exposure amount for injury to occur [and] failed to determine how much Foam Flush Bonner was exposed to." *Bonner*, 259 F.3d at 932. The Eighth Circuit rejected the argument that an expert cannot testify unless he can identify the threshold unsafe level of exposure. It affirmed the expert's opinion satisfied the *Daubert*

standard and supported causation, noting the expert explained “as small as a quarter of a teaspoon can have toxic effects, and that inhalation is a more potent exposure mechanism than is ingestion.” *Id.* This testimony sufficiently constituted “evidence from which a reasonable person could conclude that the exposure probably caused her injuries.” *Id.*

More recently, the Eighth Circuit again confirmed evidence of exposures beyond mathematical calculations satisfies both *Daubert* and plaintiff’s burden for causation. *Kirk v. Schaeffler Group USA, Inc.*, 887 F.3d 376 (2018).<sup>4</sup> In *Kirk*, the plaintiff alleged she contracted autoimmune hepatitis (AIH) from exposure to defendant’s TCE. *Kirk*, 887 F.3d at 381-82. Defendants moved to exclude her experts and for summary judgment on the grounds that her experts could not calculate the amount of TCE she was exposed to. *Id.* at 391. The court denied these motions, explaining that such calculations are not necessary because plaintiff’s medical expert was free to rely on all evidence tending to show exposure at levels that, combining with other risk factors, caused the disease:

Dr. Gilbert’s opinion is not connected to the existing data merely by her own empty assertion. It relies on a significant amount of admissible evidence to posit that [Kirk] was exposed to a significant level of TCE both in utero and while growing up in Silver Creek, by ingesting, inhaling, and absorbing TCE through her skin. While Dr. Gilbert’s report does not estimate an exact level of exposure, it explains why such an estimate is not possible. It also provides a reliable basis for her opinion that [Kirk’s] exposure to TCE was such that, over time, acting on a genetic predisposition, it caused [Kirk] to develop AIH, and it was not idiopathic [i.e., of unknown cause].

*Id.* The jury agreed with Dr. Gilbert and found defendants had caused or contributed to cause plaintiff’s disease: “defendants’ negligent handling, use, or disposal of [TCE] at the Joplin plant, or [failure] to properly warn Plaintiff of the TCE contamination, had directly caused or contributed to Kirk’s injury.” *Id.* at 382.

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<sup>4</sup> Plaintiffs’ counsel in this case also represented the plaintiff in *Kirk*.

Defendants appealed, complaining plaintiff failed to show sufficient evidence of causation. Defendants claimed not only did she fail to prove “she was exposed to a level or quantity of TCE significant enough to cause her AIH,” but her experts could not even point to a single other individual who had ever contracted AIH from TCE. *Id.*, at 390. The Eighth Circuit rejected both these arguments and upheld the jury’s verdict. It explained even though she was the only person to contract her disease from AIH and her experts could not give any level of her exposure, it was nonetheless up to the jury to decide the issue of causation:

The issue is difficult because AIH is a rare disease and what causes it has not been clearly established. While it is a known carcinogen that can cause many health issues, TCE has never been definitively identified as the cause of AIH in human beings. But Dr. Gilbert and Dr. Zizic presented substantial scientific evidence tending to establish that exposure to TCE can cause AIH, and Dr. Everett testified to extensive TCE contamination in the Silver Creek community and the many ways Kirk was exposed to that contamination for many years. We do not require “a mathematically precise table equating levels of exposure with levels of harm.” *Id.* at 1107, quoted in *Bednar v. Bassett Furniture Mfg. Co.*, 147 F.3d 737, 740 (8th Cir. 1998). Like the district court, we conclude Kirk submitted sufficient evidence of general causation to submit her claim to the jury.

*Id.*, at 390-91.

The law does not limit experts’ opinions to only levels of exposure that can be precisely calculated. Experts may consider and testify about all admissible evidence concerning exposure, regardless of whether or not they can quantify such evidence. Doing so is reliable and admissible under *Daubert* and Eighth Circuit precedence.

**B. Dr. Clark’s “Reasonable Maximum Exposure” Dose Is Consistent With the ATSDR and EPA Methodology For Exposure Analysis.**

Defendants argue that Dr. Clark’s use of Reasonable Maximum Exposure (RME) dose for each Plaintiff has no basis and results in an unsound dose calculation. Defendants’ rely on *Cano v. Everest Minerals Corp.*, 362 F. Supp. 2d 814 (W.D. Tex. 2005) for this proposition but *Cano* is neither authoritative nor persuasive on the subject of Dr. Clark’s use of RME. Defendant claims

what Dr. Clark did was more outrageous than what plaintiff's expert did in *Cano*, however Defendants' claims of outrageousness are predicated on false assertion that Dr. Clark invented his methodology. To the contrary, Dr. Clark followed the prescribed methodology of both the ATSDR and the EPA in calculating Plaintiffs' estimated doses.

RME is a well-accepted principal in dose assessment/risk analysis. Most agencies, including the EPA, endorse the use of RME. In fact, the EPA utilized this method in its 1993 Baseline Health Risk Assessment of the very sites Plaintiffs claim they were exposed to radionuclides:

In accordance with EPA guidance (EPA 1989c), intakes were estimated for a single route of exposure (e.g., incidental ingestion of soil) at a single exposure point (e.g., the HISS property). Exposure estimates have been based on the "reasonable maximum exposure" (RME) expected to occur under current and future land-use conditions.

(**Exhibit E**, Baseline Risk Assessment for Exposure to Contaminants at the St. Louis Site, St. Louis Missouri, November 1993, Pg. 3-24, 7-8). In the ATSDR's Final Public Health Assessment, it defended its use of RME to estimate the exposure and resulting risks for individuals that may have come in contact with radionuclides in the areas surrounding Coldwater Creek. (Def. Exh. C, Pg. F-14). Neither the EPA nor the ATSDR consider these to be "purely fictional doses" as Defendants argue. In fact, rather than considering such an approach to be "outrageous," as Defendants claim it is, both agencies accept it as reasonable.

Dr. Clark followed this accepted approach, using the ATSDR's RME to calculate each Plaintiff's dose using the 95% UCL of the average of their exposures. Dr Clark's 95% UCL values were derived from soil contaminant concentrations straight from the ATSDR's Public Health Assessment (**Def. Exh. C**, Pg.C-3 – C-4). To determine exposure point concentrations for past exposures, the ATSDR used the maximum concentration at several different soil depths to estimate

what could have been present at the surface. *Id.* Exposure point concentrations for particulates in air were based on soil 95% UCL values of the various contaminants and on assumptions regarding the transfer of these contaminants to air. (*See Id.*, Pg. D-1 – D-3).

Again, Dr. Clark did exactly what was prescribed by both the USEPA and the ATSDR in their own exposure estimates. For instance, in accordance with its own guidance, the EPA stated that in order to calculate the potential human exposure that might be associated with a contaminated source, use of the 95% UCL values is preferable. (**Exhibit E**, Pg. 3-13 - 3-14).

Moreover, when challenged by Defendants’ own experts on its use of the 95% UCL, rather than an area-weighted mean UCL concentration, the ATSDR wrote:

*ATSDR response: ATSDR evaluations are intended to be protective of all exposed community members. Some children and adults could have gone regularly to the same general area of the creek. Using an area-weighted mean could underestimate these exposures.*

(**Def. Exh. C.**, Pg. F-49 (emphasis in original)). The ATSDR is unequivocal in its defense of its use of the 95% UCL:

*ATSDR response: Use of the 95th percentile values for inhalation rates and other intakes follows ATSDR ’s standard practice and aligns with our goal to be protective of all potentially exposed community members.*

....

*ATSDR response: ATSDR ’s evaluations are intended to be protective of all exposed community members. Some children and adults could have gone regularly to the same general area of the creek. Therefore, we selected the highest upper confidence limit in any sector as a conservative estimate of possible exposure point concentration. We considered each radionuclide separately for this selection. In most cases, the selected values for U-238 and Ra-226 were from the same exposure unit as Th-230.*

*Id.* at F-53 and F-15 (emphasis in original).

Dr. Clark’s reliance on a the ATSDR’s data and the use of the 95% UCL did not create “purely fictional doses,” but rather was in keeping with the prescribed methods of both the EPA

and ATSDR. (See **Def. Exh. K**, Pg. 32). Providing a range of potential exposure scenarios as Dr. Clark did here is consistent with standard practice in conducting a reliable exposure analysis.

**C. Dr. Clark's "Maximum" Doses Aid the Jury By Providing a Range of Potential and Possible Exposure Scenarios**

Defendants next argue that Dr. Clark's opinions are unreliable because he calculated a maximum dose for each Plaintiff using the highest recorded concentrations of radionuclides present at the locations each Plaintiff claimed they were at. Such an approach is consistent with standard practice in conducting a reliable exposure analysis.

Defendants claim Dr. Clark's analysis is impossible because his dose reconstruction includes exposures from more than one location in a given day. But, as Dr. Clark explained in his deposition, human beings can move from one location to another in a single day.

Q. Okay. Isn't it true that the individual's exposure would not have occurred at one point in time or at one location?

**A. That is correct.**

Q. Okay. They move around; correct?

**A. They move around, yes.**

Q. And different areas that you've evaluated in your report had different concentrations of soil; correct?

**A. Correct.**

(**Def. Exh. B**, Pg. 249:9-18).

As there was nothing that restricted any Plaintiff from being exposed to radionuclides at several locations in any given day, it is more than reasonable for Dr. Clark to calculate their potential dose based on concentrations levels at those locations. While this approach may be conservative, it does not render it unreliable under *Daubert*.

Next, Defendants argue that Dr. Clark's opinions regarding Plaintiffs' maximum exposures at those locations present an "impossible scenario." The EPA disagrees with Defendants' characterization of this approach. In its Baseline Risk Assessment, the EPA states:

The UL<sub>95</sub> values of the arithmetic means of the measured radionuclides (i.e., uranium-238, radium-226, thorium-230, and thorium-232) were used to derive the concentrations of the other radionuclides in the decay series, so all values are analogous to anticipated arithmetic mean UL<sub>95</sub> values. **These values are considered to represent an upper bound of likely exposure point concentrations at each property**, which accounts for localized areas of elevated concentrations of contaminants. To account for the remote possibility that the entire area of SLDS and the city property could be developed for future residential use, the data for the SLDS and city property were combined for deriving the exposure point concentrations for the future resident scenarios at these properties.

(**Exhibit E**, Pg. 3-15(emphasis added)). For exposure analysis it conducts, the EPA uses “exposure descriptors” which are estimates for a specific point on the exposure distribution. (See **Exhibit F**, Exposure Assessment Tools by Approaches - Indirect Estimation (Scenario Evaluation) (2004), accessed at <https://www.epa.gov/expobox/exposure-assessment-tools-approaches-indirect-estimation-scenario-evaluation>). This approach establishes variable exposures scenarios due to differences among individuals, populations, spatial and temporal scales, and other factors. *Id.* According to the EPA, “variability can be addressed by estimating exposure for the various descriptors of exposure (i.e., central tendency, high-end, or bounding) to estimate points on the distribution of exposure.” *Id.* The EPA states that these high-end estimates of exposure, “are generally considered to be more realistic or more likely to occur compared with bounding estimates.” *Id.* The following descriptors all account for the individuals at the high end of the exposure distribution:

**Reasonable maximum exposure (RME)** – the highest exposure reasonably likely to occur, generally assumed to be in the range of the 90th and 99.9th percentiles (U.S. EPA, 2001)

- **Reasonable worst-case exposure** – the lower part of the high-end exposure range, which is above the 90th percentile but below the 98th percentile (U.S. EPA, 1992)
- **Maximum exposure** – the range above the 98th percentile (U.S. EPA, 1992)

*Id.* (emphasis in original). The EPA goes on to endorse the use of these high-end estimates in determining possible exposure scenarios:

These terms all refer to exposures that are within the population distribution and not outside the distribution. The terms are expected to describe "an individual who exists, or is thought to exist, in the population." The worst-case scenario, by contrast, describes a situation of exposure that is "a statistical possibility that may or may not occur in the population" (U.S. EPA, 1992).

As the exposure estimate moves higher within the percentile range, the level of uncertainty increases. These high-end estimates are intended to assess exposures that are higher than average, but still within a realistic, reasonable anticipated range.

*Id.* This is precisely the approach Dr. Clark used in analyzing each Plaintiffs' exposures to radionuclides. Dr. Clark presented calculations for a range of potential exposures for the jury to consider in determining whether Plaintiffs' exposures were enough to cause or contribute to cause their respective injuries. As this method is derived from and endorsed by the EPA it is reliable and does not create an "unrealistic" exposure scenario as Defendants would have it. Therefore Dr. Clark's opinions regarding maximum exposure are accepted by the scientific community and admissible under *Daubert*.

### **CONCLUSION**

Defendants' motion to exclude Plaintiffs' experts and dismiss this case contains nothing more than cross examination points. Dr. Clark is an expert toxicologist, exposure analyst, and air modeler who has studied the issues presented in this case. He relies on scientifically accepted and reliable methodologies to quantify the amount of Plaintiffs' exposure that can be quantified. He also evaluated all other exposure evidence and realized the total amount of radiation. In short, Dr. Clark is qualified to offer his opinions and adequately explains the reliable methodologies that support them. His testimony should not be excluded.

WHEREFORE, for the reasons stated above, Plaintiffs respectfully request the Court deny Defendants' Motion to Exclude the Expert Testimony of Dr. James Clark.

Respectfully Submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on the 29<sup>th</sup> day of September, 2021, I electronically filed the above with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to counsel of record.

/s/ Colin W. McClain

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